UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,129	05/16/2001	Man Sung Co	202617USOPCT	3422

22850 7590 10/03/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,129	CO ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21 and 23-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21 and 23-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: NOTICE TO COMPLY BUT SEE OFFICE ACTION

DETAILED ACTION

1. Applicant's amendment, filed 11/12/02, has been entered.
Claims 1-17, 20 and 22 have been canceled.
Claims 23-27 have been added.
Claims 18, 19 and 21 have been amended.

Claims 18-19, 21 and 23-27 are pending.

2. Applicant's request for consideration of documents cited in the International Search Report is acknowledged.

However, neither the references nor the International Search Report were found upon a review of the documents in this scanned application.

Applicant is invited to provide an Information Disclosure Statement and the cited references to complete this file application.

Further, it is noted references cited in the Search Report would not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the reference printed on such resulting patents on a separate listing, preferably on a PTO 1449 or PTO/SB/08A and 08B form, must be filed.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Also, see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

5. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18-19, 21 and 23-27 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: the recitation of claim 18(a) and (b) as it reads on the CDRs and framework regions of generic humanized immunoglobulins employed in the claimed methods of treating thrombotic diseases or atherosclerosis.

Applicant's amendment, filed 11/12/02, directs written support to pages 15-17, Figures 2A-2B and Example 2 and original claim 18 for the recitation of claim 18(a) and (b).

Pages 15-17, Figures 2A-2B and Example 2 and original claim 18 of the instant application provide for CDR sequences and framework regions for the particular humanized AjvW-2 von Willebrand factor-specific antibody.

The recitation of claim 18(a) and (b) now represents a departure from the specification and claims as originally filed. Applicant's reliance on the disclosure of the humanized AjvW-2 antibodies does not provide sufficient direction and guidance to the "features" currently claimed. The current claims broaden the instant disclosure to any humanized immunoglobulin comprising the certain AJvW2-derived CDR sequences and I3R framework regions. The claims do not recite "AJvW2" as the source material of the claimed humanized antibodies. The claims do not recite the von Willebrand factor specificity.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

In addition, the following is noted with respect to the specific sequences set forth in claim 18(a).

The sequences set forth in claim 18(a) do not set forth SEQ ID NOS. as required by 37 CFR 1.821(d). Also see MPEP 2422

This application (the amino acid sequences set forth in current claim 18(a) contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825 (see the specification at page 10, line 22). However, this application fails to comply with the requirements set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence.

However, applicant is reminded that the instant claims are currently rejected under 35 USC 112, first paragraph, new matter.

Therefore, sequence compliance would not be required if the recitation of instant claim 18(a) is canceled.

9. Claims 18-19, 21 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating patients having or at risk of a thrombotic disease or atherosclerosis with humanized immunoglobulin comprising the claimed sequences that are "specific for von Willebrand factor", does not reasonably provide enablement for any "humanized immunoglobulin comprising the claimed sequences". The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not provided sufficient guidance and direction to reliance on accomplishing the claimed therapeutic methods with humanized antibodies comprising the claimed sequences other than humanized antibodies that are "specific for von Willebrand factor". Although the claimed CDR sequences are derived from the particular humanized AjvW von Willebrand factor-specific antibody, the claims do not recite the von Willebrand factor specificity. Immunoglobulins are highly polymorphic. In the absence of defining the von Willebrand specificity, antibodies comprising the claimed CDR sequences do not necessarily have the appropriate specificity in order to accomplish the claimed methods.

Applicant has provided enablement for antibodies that bind von Willebrand factor. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable any "humanized immunoglobulin comprising the claimed sequences.

Applicant should amend the claims to recite the von Willebrand factor specificity to obviate this rejection.

10. Claims 18-19, 21 and 23-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

Claims 18-19, 21 and 23-27: It is apparent that the "I3R" antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line/hybridoma which produces this immunoglobulin. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

It has been noted that if the claimed and disclosed amino acid sequences or nucleic acid sequences set forth in the instant application encode the entire "I3R" antibody; then a deposit for said "I3R" expressing cell line/hybridoma) is not required. The sequence of an entire immunoglobulin satisfies the biological deposit of said antibody / immunoglobulin.

However, it appears that applicant is attempting to incorporate essentially subject matter by reference to a publication, then the reference and the direction to that reference for the support of the sequence of the "I3R" immunoglobulin must be disclosed in the specification as filed.

If this is so, then the following is noted.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United states or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

The referencing application must include (1) an abstract, (2) a brief summary of the invention, (3) an identification of the referenced patent or application, (4) at least one view in the drawing in those applications admitting of a drawing, and (5) one or more claims. Particular attention should be directed to specific portions of the referenced patent or application.

Applicant is reminded to provide said Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the essential subject of the amino acid sequence defining the claimed "I3R" immunoglobulin, if the appropriate direction and reference can be found in the specification as filed.

If the appropriate direction and reference cannot be found in the instant specification as filed, then applicant should not attempt to bring the sequence information for the I3R immunoglobulin, as that would be subject to a rejection under 35 USC 112, first paragraph, new matter.

11. Claims 18-19, 21 and 23-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 18-19, 21 and 23-27 are indefinite in that the sequences do not have SEQ ID NOS., as required by 37 CFR 1.821(d). Also see MPEP 2422.

Again, applicant is reminded that the instant claims are currently rejected under 35 USC 112, first paragraph, new matter.

Therefore, sequence compliance would not be required if the recitation of instant claims 18(a) is canceled.

B) Claims 18-19, 21 and 23-27 are indefinite in the recitation of "I3R" because its characteristics are not known. The use of "I3R" antibody as the sole means of identifying the claimed antibody renders the claims indefinite because this is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct cell lines.

Amending the claims to recite the appropriate ATCC Accession Numbers or sequences would obviate this rejection.

C) Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

12. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 18-19, 21 and 23-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,613,328 (Co et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant claims, as being drawn to the same or nearly the same methods of treating

thrombotic disorders or atherosclerosis with the same or nearly the same the von Willebrand factor-specific humanized AjvW antibodies. Further, the instant limitations, including the sequences set forth in instant claim 18(a) and (b) are derived from the von Willebrand factor-specific humanized AjvW antibody disclosed and claimed in U.S. Patent No. 6,613,328.

13. Claims 18-19, 21 and 23-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20 of copending application Serial No. 10/289,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of treating thrombotic disorders or atherosclerosis with the same or nearly the same methods of treating thrombotic disorders or atherosclerosis with the same or nearly the same the von Willebrand factor-specific humanized AjvW antibodies. Further, the instant limitations, including the sequences set forth in instant claim 18(a) and (b) are derived from the von Willebrand factor-specific humanized AjvW antibody disclosed and claimed in copending USSN 10/289,181.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. No claim allowed.

Given the claims and prosecution of U.S. Patent No. 6,613,328 (Co et al.), it appears that the instant claims which rely upon the limitations, drawn to sequences set forth in instant claim 18(a) and (b) are derived from the von Willebrand factor-specific humanized AjvW antibody disclosed and claimed in U.S. Patent No. 6,613,328. Accordingly, the claims appear free of the prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 30, 2003